

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Substance Abuse and Mental Health Services Administration
Center for Mental Health Services**

**Guidance for Applicants (GFA) No. SM-02-015
Part I - Programmatic Guidance**

Title: State Mental Health Data Infrastructure Grants

Short Title: Data Infrastructure Grants

Application Due Date:
July 24, 2002

Bernard S. Arons, M.D.
Director, Center for Mental Health Services
Substance Abuse and Mental Health
Services Administration

Charles G. Curie, M.A., A.C.S.W.
Administrator
Substance Abuse and Mental Health
Services Administration

Date of Issuance: May 2002
Catalog of Federal Domestic Assistance (CFDA) No. 93.243

Authority: Section 520A of the Public Health Service Act, as amended and subject to the availability of funds

Table of Contents

Agency	1
Action and Purpose	1
Key Questions	3
Grant Application Technical Assistance	3
Matching Requirement	3
Who Can Apply?	3
Application Kit	4
Where to Send the Application	4
Application Dates	4
How to Get Help	4
Funding Criteria	5
Post-award Requirements	5
Program Background and Overview	5
Detailed Information on What to Include in Your Application	
Face Page	7
Abstract	7
Table of Contents	7
Budget Form	7
Program Narrative and Support Documentation	7
Appendices	8
Assurances	8
Certifications	8
Disclosure of Lobbying Activities	8
Checklist	8
Intergovernmental Review (E.O. 12372)	8
Project Narrative - Sections A through E	9
Confidentiality and SAMHSA Participant Protections	13
Appendix A: Basic Measures	
Appendix B: Developmental Measures	
Appendix C: Sixteen State Indicator Pilot Measures	
Appendix D: Guidelines for Consumer and Family Participation	
Appendix 1: Table of State Status for Basic, Developmental, and Optional Measures	

Agency

Department of Health and Human Services (DHHS), Substance Abuse and Mental Health Services Administration.

Action and Purpose

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS), announces the availability of fiscal year 2002 funds for State Mental Health Data Infrastructure Grants for State Uniform Reporting. Approximately \$550,000 will be available for seven awards. The average annual award will be \$100,000 for each State Mental Health Authority and \$50,000 for each U.S. Territory (direct and indirect).

Annual awards may be requested for 3 years, contingent upon the availability of funds and progress achieved.

The purpose of this program is to develop and sustain State and community data infrastructure that helps promote comprehensive, community-based systems of care for all children and adults with mental illness or at risk of developing mental illness. Information systems are important tools to improve accountability, increase access, target resources, and continuously improve quality of care.

In this announcement, four grants to State Mental Health Authorities (SMHAs) and three grants to the Mental Health Authority in U.S. Territories are available for developing

infrastructure for future data compilation of the Uniform Data Reporting under the Block Grant Program, to be reported as part of the CMHS Block Grant Application. Developing data capacity for the CMHS 16-State Indicator Pilot Grant program is also part of the effort for States that can complete Uniform Reporting Measures. The grant project is a collaborative effort of the Survey and Analysis Branch and the State Planning and Systems Development Branch, within the Division of State and Community Systems Development.

Grantees will be expected to work with CMHS in developing and evaluating the statewide capacity to use common definitions provided in this application for Basic Measures (Appendix A), Developmental Measures (Appendix B), and, as appropriate, Optional Measures (Appendix C) as part of the State data infrastructure.

The Basic and Developmental Measures are designed to answer five basic questions: 1) What are the mental health service needs of the populations in your State? 2) Who in your State gets access to publicly funded mental health services? 3) What types of services are being provided in your State? 4) What are the consumer outcomes for the services provided? 5) What financial resources are expended for the services?

Optional Measures are those measures that have been developed in the 16-State Indicator Pilot Grant Project but are not part of the Basic or Developmental Measures. Examples include use of atypical anti-psychotic medications, recovery, cost, and functioning and symptoms measurement.

By 2005, each State will be expected to report the Basic Measures and as many Developmental Measures as possible as part of the Block Grant application.

The grant application must reflect a partnership between mental health planning and data programs in the State. It is strongly recommended that joint planner and data representatives be identified by the State as joint Principal Investigators for the grant project.

In addition to grant support, technical assistance will be available to States to assist in the purposes of the grants, and to assist in the integration of various national efforts that are supporting quality improvement and data infrastructure development.

This grant effort is also intended to facilitate the development of data infrastructure related to the Health Insurance and Portability Act of 1996 (HIPAA): HIPAA electronic transmission requirements, evolution of integrated information systems across service sectors, and electronic recording and reporting of information. Within 18 months, States will be required to submit claims for payment electronically using HIPAA electronic transmission data standards. Work under this grant will facilitate compliance with these requirements.

The grant strongly supports project coordination with the respective State Mental Health Planning Councils. The grant effort also encourages States to establish collaborative partnerships for integrating SMHA information systems with other information systems such as Medicaid, community health, maternal and child

health, school health, criminal justice, child welfare, and substance abuse to make a more complete picture of the public mental health system available. Where relevant to the Basic and Developmental Measures, the States are encouraged to address the mental health measures and overarching health goals of Healthy People 2010.

States are encouraged to develop infrastructure capacity for electronic recording and reporting of data. In this effort, States should consider adopting a unique client identifier as part of their management information system.

Grantees will be expected to work with CMHS in implementing all aspects of this grant to create both nationwide and statewide capacity to develop consistent measures for planning and service implementation.

CMHS is currently working on a broader effort for developing the data infrastructure for Basic, Developmental, and Optional Measures. This effort includes data definitions, measures, and standards that build upon and expand the Mental Health Statistics Improvement Program (MHSIP) data standards and other projects such as the MHSIP Consumer-Oriented Mental Health Report Card and the 16-State Indicator Pilot Grant Project. The enrollment and encounter core data sets from this effort encompass the data standards for the Basic Measures; the outcome and performance indicator core data sets from this effort encompass the data standards for the Developmental and Optional measures. All data sets are designed to be fully compliant with the HIPAA automated transaction requirements. Also, in the project the States will respond to the Government Performance

and Results Act (GPRA), which requires demonstrated accountability through quantitative measures. It is anticipated that the measures will be interpreted and defined through the grant project.

Key Questions

In developing the application for the grant proposal, the applicant should consider the following key requirements:

1. Does the applicant have the essential data infrastructure to collect, process, and report **all** of the Basic Measures throughout the SMHA information system? By 2005, the State will be expected to report these Basic Measures as part of the annual Block Grant application.
2. Does the applicant have the essential data infrastructure to collect, process, and report **all** of the Developmental Measures throughout the SMHA information system?
3. Does the applicant have the essential data infrastructure to collect, process, and report selected Optional Measures throughout the SMHA information system as defined in the 16-State Indicator Pilot Project? Work on Basic and Developmental Measures should precede work on Optional Measures.

Grant Application Technical Assistance

A pre-grant submission technical assistance conference call will be held for grant applicants to assist State and U.S. Territory

representatives in the development of their applications. An announcement regarding the time of the conference call will be provided to eligible States and U.S. Territories following the grant announcement. In the call, key components of the grant will be discussed. For those unable to participate in the call, CMHS grant project officers (cited in the GFA, page 4) will provide assistance.

Matching Requirement

An award may be made ... “only if the applicant agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs....Non-Federal contributions... may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.” Sec. 3404, Data Infrastructure Projects, Part C of title XIX of the Public Health Service Act (42 U.S.C.) 300y et seq., amended Sec. 1971, Data Infrastructure Development.

Who Can Apply?

The following are eligible to apply:

- / Applicants must be State Mental Health Authorities or the equivalent in the District of Columbia.

- / Applicants must be State Mental Health Authority equivalents in U.S. Territories.
- / **Previous grantees in this program are not eligible to apply, as they are already conducting the activities supported by the grant.**

Application Kit

Application kits have two parts. Part I is different for each GFA. Part II has general policies and procedures that apply to all SAMHSA grant and cooperative agreements. You will need to use both Parts I and II for your application. **This document is Part I.**

To get a complete application kit, including Parts I and II, you can:

Call the Knowledge Exchange Network at 1-800-789-2647, or download from the SAMHSA site at www.SAMHSA.gov.

Where to Send the Application

Send the original and two copies of your grant application to:

SAMHSA Programs
Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC-7710
Bethesda, MD 20892-7710*

*Change the zip code to 20817 if you use express mail or courier service.

Please note:

1. Use application form PHS 5161-1.
2. Be sure to type:
“GFA # SM-02-015 Data Infrastructure Grants” in Item Number 10 on the face page of the application form.
3. **Effective immediately, all applications MUST be sent via a recognized commercial or governmental carrier. Hand-carried applications will not be accepted.**

Application Dates

Your application must be received by July 24, 2002.

Applications received after this date will only be accepted for the appropriate receipt date if they have a proof-of-mailing date from the carrier no later than July 17, 2002.

Private metered postmarks are not acceptable as proof of timely mailing. Late applications will be returned without review.

How to Get Help

For questions on the Mental Health Block Grant Program, contact:

Nainan Thomas, Ph.D.
Public Health Adviser
Room 15C-26
5600 Fishers Lane
Rockville, MD 20857
(301) 443-4257
E-mail: nthomas@samhsa.gov

For questions on Measures and the GFA Application contact:

Olinda González, Ph.D.
Public Health Adviser
Room 15C-04
5600 Fishers Lane
Rockville, MD 20857
(301) 443-2849
E-mail: ogonzale@samhsa.gov

For questions on grants management issues, contact:

Steve Hudak
Division of Grants Management
Substance Abuse and Mental Health Services Administration
Room 13-103
5600 Fishers Lane
Rockville, MD 20857
(301) 443-9666
E-mail: shudak@samhsa.gov

Funding Criteria

Decisions to fund a grant are based on:

1. The strengths and weaknesses of the application as shown by a CMHS Review Committee.

- C Although funds are allocated for State Mental Health Authorities and U.S. Territories that have not been awarded a previous data infrastructure grant, an applicant must be favorably reviewed to be eligible for funding.

2. Availability of funds.

Post-award Requirements

Grantees will be expected to participate in monthly conference calls and annual meetings held in Washington DC, to review grant progress. Travel arrangements should be made for these meetings in grant budgets, with the exception of U.S. Territories, for which other arrangements will be made.

Grantees will be expected to participate in peer-to-peer collaboration throughout the grant effort.

Grant awardees will be required to submit:

1. Grantee progress reports at annual meetings.
 2. Information requested by SAMHSA to comply with the Government Performance and Reporting Act (GPRA).
 3. A final report at the end of the project period summarizing results of the three year effort, including ability to compile specific measures as indicated in Grant application.
-

Program Background and Overview

Data Standards and Definitions

For the past 25 years, MHSIP has developed and implemented consensus-based data standards for mental health services. The most recent completed edition of these standards, FN 10, was published in 1989 and is currently being updated. Another significant product of MHSIP has been the MHSIP Consumer-Oriented Mental Health Report Card recommending selected performance and outcome indicators for implementation in the field (1996). Version 2 of the report card is currently being developed. This work was followed by a collaborative effort of MHSIP and the CMHS State Block Grant Program, in which the 5-State Feasibility Project (1997) and the 16-State Indicator Pilot Grant Project (1998-2001) further refined and piloted indicators and measures for comparable implementation in the States. These two projects used the framework developed by the National Association of State Mental Health Program Directors (NASMHPD) President's Task Force on Performance Measures. It is noteworthy to mention that the NASMHPD framework was based on the MHSIP Consumer-Oriented Mental Health Report Card. This grant effort builds upon all of these projects to improve both data infrastructure and comparable reporting at the State and national levels.

Developing the Capacity for Uniform Reporting

Uniform data in the public mental health system is required to improve planning and accountability for the Community Mental Health Services Block Grant and for the oversight of community mental health services. Block grant funds further the capacities of the publicly funded community mental health system in each State. The flexible funding of the block grant allows States to fill gaps and fund new and innovative services. To understand the value and use of block grant funds, it is critical that both CMHS and the SMHAs have accurate and uniform data on the public mental health system in each State. The data requested through the 12 Basic Tables (Basic Measures), included as part of the Block Grant application for FY 2002-2004 (Section V), and the seven Developmental Tables, which are not included as part of the block grant application but made available through this grant announcement, are designed to address this need.

It is expected that this grant will assist States in developing their infrastructure capacities to begin reporting data on the 12 Basic Tables as part of the block grant application (Section V) beginning with FY 2003 and in full by FY 2005, and all data requested under the Developmental Tables by a separate submission by the end of this grant period. If the State fiscal year is different from the Federal fiscal year, the State's data report can be based on the data available for the last completed State fiscal year. All client data must be aggregated at the State level. No individual client data are requested or should be submitted for these tables. State identifiers are required for each table. CMHS will create, on its own, all derived measures from the primary data provided by the States. CMHS will

review the State-submitted data and make requests for revision, clarification, or additional information as appropriate from the SMHAs.

Focus of the Current Grant

This grant effort encourages linkage between MHSIP developments and the CMHS Block Grant reporting needs. This collaborative effort will assure uniform State data reporting for accountability and planning, utilizing an information framework that incorporates essential data standards, including quality tools and measures. This collaborative work will result in new methodologies and approaches that will benefit the entire mental health field.

The Uniform Data Reporting for the mental health performance partnership program addresses basic utilization and selected outcome measures (Appendixes A and B). If State applicants can document that they will be able to report on Basic and Developmental Measures by 2005, they may then also propose Optional Measures.

Detailed Information on What to Include in Your Application

In order for your application to be **complete and eligible**, it must include the following in the order listed. Check off areas as you complete them for your application.

1. FACE PAGE

Use Standard Form 424. See Appendix A in Part II for instructions. In signing the face page

of the application, you are agreeing that the information is accurate and complete.

2. ABSTRACT

Your total abstract may not be longer than 35 lines.

In the first five lines or less of your abstract, write a summary of your project that can be used in publications, reporting to Congress, or press releases.

3. TABLE OF CONTENTS

Include page numbers for each of the major sections of your application and for each appendix.

4. BUDGET FORM

Standard Form 424A. See Appendix B in Part II for instructions.

5. PROGRAM NARRATIVE AND SUPPORT DOCUMENTATION

These sections describe your project. The program narrative is made up of Sections A through E. More detailed information on Sections A-E follows #10 of this checklist. Sections A-E may not be no longer than 25 pages.

< **Section A** - SMHA Status Related to Grant Project

< **Section B** - Detailed Work Plan

Section C - Project Management

< **Section D** - Stakeholder Participation

< **Section E - Utilization of Information**

The supporting documentation for your application is made up of sections F through I.

There are no page limits for the following sections, except for Section H, the Biographical Sketches/Job Descriptions.

< **Section F - Literature Review** (not applicable)

< **Section G - Budget Justification, Existing Resources, Other Support**

Fill out sections B, C, and E of the Standard Form 424A. Follow instructions in Appendix B, Part II. For Section B, provide matching or in-kind budget justification.

You must provide a narrative justification of the items included in your proposed budget, as well as a description of existing resources and other support you expect to receive for your project.

< **Section H - Biographical Sketches and Job Descriptions**

☐ Include a biographical sketch for the project director and for other key positions. Each sketch should be no longer than **2 pages**. If the person has not been hired, include a letter of commitment from him or her with a biographical sketch.

☐ Include job descriptions for key personnel. They should no be longer than **1 page**.

☐ ***Sample sketches and job descriptions are listed in Item 6 in the Program Narrative section of the PHS 5161-1.***

< **Section I - Confidentiality and SAMHSA Participant Protection (SPP)**

The seven areas you need to address in this section are outlined after the Project Narrative description in this document.

' **6. APPENDICES 1 and 2**

☐ Use only the appendices listed below.

☐ **Do not** use appendices to extend or replace any sections of the Program Narrative (reviewers will not consider them if you do).

☐ **Do not** use more than **25 pages** for the appendices.

Appendix 1: Table of State Status for Basic and Developmental Measures

Appendix 2: Stakeholder Letters of Support

' **7. ASSURANCES**

Non-Construction Programs. Use Standard form 424B found in PHS 5161-1.

' **8. CERTIFICATIONS**

Use the Certification forms which can be found in PHS 5161-1. See Part II of the GFA for instructions.

' **9. DISCLOSURE OF LOBBYING ACTIVITIES**

Use Standard Form LLL (and SF LLL-A, if needed), which can be found in Form PHS 5161-1. Part II of the GFA also includes information on lobbying prohibitions.

' **10. CHECKLIST**

See Appendix C in Part II for instructions.

' **11. INTERGOVERNMENTAL REVIEW (E.O. 12372)**

Executive Order (E.O.) 12372 sets up a system for State and local government review of applications. Applicants (other than Federally recognized Indian tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert him/her to the prospective application(s) and receive any necessary instructions on the State's review process. Part II of the GFA provides additional information about E.O. 12372.

Project Narrative— Sections A Through E Highlighted

Your application consists of addressing Sections A through I. **Sections A through E, the project narrative parts of your application, describe what you intend to do with your project.** Below you will find detailed information on how to respond to Sections A through E.

K Sections A through E may not be longer than 25 pages.

K The number of points after each main heading shows the relative importance assigned to that section.

K The applicant is to address cultural competence as appropriate, and as stated in the GFA narrative. Cultural competency is defined as a set of behaviors, attitudes, and policies that come together on a continuum; to ensure that a system, agency program, or individual can function effectively and appropriately in diverse cultural interactions and settings. It promotes the understanding, appreciation, and respect of cultural differences and similarities within, among, and between groups. Cultural competency is a goal that a system, agency, program, or individual continually aspires to achieve.

Section A: SMHA Status Related to Grant Project **(15 points)**

C Status of Current SMHA Information System

- < Generally describe how the SMHA is organized within the State, and provide a background on the current State mental health information system data collection and reporting capabilities. *In most States, the SMHAs include the respective mental health organizations that are operated and funded and the consumers who are served. For practical purposes, this usually includes the Medicaid clients served by these organizations.*
- < Provide a general outline of domains currently addressed and utilization and performance measures being collected and reported. To what extent are these domains and measures consistent with the data items in Appendices A, B, and C?
- < Provide a summary of the sociodemographic characteristics of populations being served, reporting time frames, and reporting entities, and the ability to collect unduplicated counts of persons served.
- < Indicate the number and types of service organizations reporting data, staffing for data collection, computer hardware and software support, and administrative and organizational processes.
- < Describe the State's ability to achieve a unique count of clients, and provide State's plans for this capability in the future.

- < Indicate the State's experiences and accomplishments with past and current MHSIP grants.
- < Describe the current technical and programmatic data challenges that remain in State data collection and reporting.

C State data collection and reporting capabilities related to Basic, Developmental, and Optional Measures

- < Generally discuss the capacity of the State mental health information system related to the Basic, Developmental, and Optional Measures.
- < Using the "Table of State Status for Basic and Developmental Measures" (Appendix 1), indicate those measures that are already collected and that can already be reported at the State level. Also indicate those measures that cannot be collected and reported, and describe those measures (and time line) that are proposed to be collected and reported by the end of year 3 in the grant project. List and provide the same information, if selected, for Optional indicators. Please refer to *Key Questions* provided on page 4.

Section B: Detailed Work Plan (40 points)

Detailed 3-Year Work Plan

Provide a detailed plan for developing the infrastructure for the Basic, Developmental, and Optional Measures, as appropriate, within the 3-year time frame of the grant. To illustrate feasibility of the plan, indicate how data system

administration, resources, and programs will be available and accessible to facilitate implementation of proposed measures.

For the Basic, Developmental, and Optional Measures (as appropriate), please indicate how data infrastructure will be developed. *(Please refer to websites mhsip.org or mentalhealth.org/funding/ for the Uniform Reporting data definitions and 16-State Indicator Pilot project operational definitions. Please note that the some of the measures are still in developmental stages and will be provided to States upon completion).*

Include in your answer the following:

- , Describe the sources from which the measures will be collected.
- , Describe the processes that will take place in data collection.
- , How will data be incorporated into the overall State management information system? Include data processes at the local level.
- , What measures will be taken to assure data quality and integrity in terms of error-free data and elimination of duplication?
- , What will be the timelines for data collection?
- , Indicate plans and processes for compliance with HIPAA requirements.
- , Indicate plans for collaboration with other entities operating relevant information

systems, and plans for moving toward electronic recording and reporting of data.

If there is a measure(s) in which data collection would not be possible, the applicant must fully state reasons for this, and, if possible, provide a proxy measure that can be collected.

Cultural Competence

In the plan provide assurances that data will be collected on race/ethnicity and will be integrated into the project, and that assessment of race/ethnicity data is or will be instituted for SMHA program planning for minority populations. Indicate how relevant assessment and planning has been or will be instituted for minority populations.

Continuation of Effort

In the plan, provide assurances of State capacity, resources, and support for continued implementation and reporting of proposed data infrastructure measures once the grant ends.

Assurances of Participation

Provide assurances that the grantee will work with CMHS throughout the period of the Grant.

Section C: Project Management (20 Points)

Grant Project Management Plan

Provide a management plan for the project to include:

- , A detailed description of how budget resources will be applied.
- , A detailed timetable for year 1 activities/tasks and an overall timeline for the grant project.
- , Critical management paths for accomplishing each task proposed.
- , A Gantt chart of management activities.

Provide information on project monitoring activities, including:

- , Assigned tasks, responsibilities, and goals of staff and/or consultants.
- , How performance goals and objectives will be monitored and evaluated.
- , Evaluation criteria for task performances or activities of staff or consultants.
- , How problems that arise will be resolved.

Assurances

- , Indicate how staff will be trained, when appropriate, to develop knowledge of race/ethnicity, age, gender, and other features of cultural competence, particularly as relevant to data utilization, performance measures and planning, and decision support.
- , Describe how the SMHA will incorporate the grant project into its own management and planning organization.
- , Provide assurances and a description of how the grant project management will be linked

to data confidentiality efforts, and how the project management will assure continuous confidentiality policies and practices throughout the grant effort.

- , Describe the relevant experience of the applicant organization and collaborating agencies to successfully complete the project.

Staffing

Describe projected staffing for the project. Include:

- , Key personnel, titles, major functions, and supervisors.
- , Evidence that loaned staff will be available for the required time.
- , Position descriptions and résumés for all key professional staff to be paid by the grant, to be included in Section F.
- , Identification of technical assistance consultants, or types of consultant expertise required for the project. To the degree practicable, provide assurances that consultants are available for the proposed assignments.

(Place any résumés, biographical information, and job descriptions in Section H, entitled Biographical Sketches/Job Descriptions).

Section D: Stakeholder Participation **(15 points)**

Stakeholder participation is supported in grant activities throughout the life of the grant. Please refer to Appendix **D**.

after the merits of the application have been considered.

- , Provide letters of support from key organizations and agencies involved in this grant application and/or that will be involved in the grant project (submit in Appendix 2). Absence of such letters should be explained by a statement in this Appendix. Letters that indicate plans for continued involvement in the grant process are strongly supported.
- , Describe the initial and ongoing participation of key SMHA stakeholders in the grant project activities. This can include participation of key SMHA managers; the SMHA Commissioner; other State representatives, as appropriate; the State Mental Health Planning Council; primary consumers, family members, providers, and community leaders; and representation from the community.
- , If stakeholder participation is a new activity for the SMHA, describe how stakeholders will be identified and included in the grant project activities.

Section E: Utilization of Information
(10 points)

Indicate how information produced under the infrastructure developed through this grant will be used directly for State planning and management activities.

NOTE: Although the **budget** for the proposed project is not a review criterion, the Review Group will be asked to comment on the budget

Confidentiality and SAMHSA Participant Protections (SPP)

You must address seven areas regarding confidentiality and SAMHSA participant protection in your supporting documentation. However, no points will be assigned to this section.

This information will:

- C Reveal if the protection of participants is adequate or if more protection is needed.
- C Be considered when making funding decisions.

Some projects may expose people to risks in many different ways. In Section I of your application, you will need to:

- C Report any possible risks for people in your project.
- C State how you plan to protect them from those risks.
- C Discuss how each type of risk will be dealt with, or why it does not apply to the project.

The following seven issues must be discussed:

Ø Protection of Clients and Staff from Potential Risks

- C Identify and describe any foreseeable physical, medical, psychological, social, legal, or other risks or adverse effects.
- C Discuss risks that are due either to participation in the project itself, or to the evaluation activities.
- C Describe the procedures that will be followed to minimize effects of or protect participants against potential health or confidentiality risks. Make sure to list potential risks in addition to any confidentiality issues.
- C Give plans to provide help if there are adverse effects on participants.
- C Describe alternative treatments and procedures that might be beneficial to the subjects where appropriate.
- C Offer reasons if you do not decide to use other beneficial treatments.

Ü Fair Selection of Participants

- C Describe the target population(s) for the proposed project. Include age, gender, and racial/ethnic background. Address other important factors, such as homeless youth, foster children, children of substance abusers, pregnant women, or other special population groups.
- C Explain the reasons for using special types of participants, such as pregnant women, children, institutionalized or mentally disabled persons, prisoners, or persons likely to be vulnerable to HIV/AIDS.

C Explain the reasons for including or excluding participants.

C Explain how you will recruit and select participants. Identify who will select participants.

Ü Absence of Coercion

C Explain if participation in the project is voluntary or required. Identify possible reasons why it is required (e.g., court orders requiring people to participate in a program).

C State how participants will be awarded money or gifts (if you plan to pay them).

C State how volunteer participants will be told that they may receive services and incentives even if they do not complete the study.

Ü Data Collection

C Identify from whom you will collect data, (e.g., participants themselves, family members, teachers, and others). Explain how you will collect data and list the site. Will you use school records, interviews, psychological assessments, observation, questionnaires, or other sources?

C Identify what, if any, type of specimen (e.g., urine, blood) will be used. State if the material will be used just for evaluation and research or for other uses. Also, if necessary, describe how the material will be monitored to ensure the safety of participants.

C Provide in Appendix 3, “Data Collection Instruments/Interview Protocols,” copies of all available data collection instruments and interview protocols that you plan to use.

Ü Privacy and Confidentiality

C List how you will ensure privacy and confidentiality. Include who will collect data and how it will be collected.

C Describe:

- < How you will use data collection instruments.
- < Where data will be stored.
- < Who will or will not have access to information.
- < How the identity of participants will be kept private (e.g., through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data).

NOTE: If applicable, grantees must agree to maintain the confidentiality of alcohol and drug abuse client records, according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

Ý Adequate Consent Procedures

C List what information will be given to people who participate in the project. Include the nature and purpose of their participation. Include how the data will be used and how you will keep the data private.

C State:

- < If their participation is voluntary.
- < Their right to leave the project at any time without problems.

- < Risks from the project.
- < Plans to protect clients from these risks.

- C Explain how you will get consent from youth, the elderly, people with limited reading skills, and people who do not use English as their first language.

Note: If the project poses potential physical, medical, psychological, legal, social, or other risks, you should get written informed consent.

- C Indicate whether you will get informed consent from participants or from their parents or legal guardians. Describe how the consent will be documented: Will you read the consent forms? Will you ask prospective participants questions to be sure they understand the forms? Will you give them copies of what they sign?
- C Include sample consent forms in Appendix 4, "Sample Consent Forms." If needed, give English translations.

Note: Never imply that the participant waives or appears to waive any legal rights, may not end involvement with the project, or may release your project or its agents from liability for negligence.

- C Describe whether separate consents will be obtained for different stages or parts of the project. For example, will they be needed for both the treatment intervention and for the collection of data. Will individuals who do not consent to having individually identifiable data collected for evaluation

purposes be allowed to participate in the project?

P Risk/Benefit Discussion

- C Discuss why the risks are reasonable when compared with expected benefits and importance of the knowledge from the project.